

REMARKS

The present application relates to methods for detecting a mammalian troponin molecule and for distinguishing between a mammalian troponin molecule and an avian troponin molecule in animal feed. The methods include assays that employ ligands for the detection of mammalian troponin. Claims 10-13, 15-17 and 20 are pending. Claims 1-9, 14, 18 and 19 are cancelled. Applicants reserve the right to pursue the subject matter of cancelled claims in a divisional or continuation application. Claims 10 and 20 are currently amended. Support for the amendments is found throughout the specification and original claims, and no new matter is introduced. In light of the following remarks, favorable consideration of the present application is respectfully requested.

Elections/Restrictions

In the Non-Final Office Action mailed February 5, 2008, the Examiner stated that newly added Claim 20, filed October 31, 2007, is distinct from the invention originally elected because SEQ ID NOs: 3-6, 9-13 and 15-35 do not share physical and functional characteristics. Applicants respectfully disagree.

Applicants submit new Claim 20 is narrower in scope than pending Claim 10. For example, **Claim 20 is identical to Claim 10 with respect to limitations a) and b).**

Furthermore, the final limitation of Claim 10 (last three lines) recites SEQ ID NOs: 2-6, 9-13 and 15-35 which is **broader** in scope than Claim 20 (that recites SEQ ID Nos: 3-6, 9-13 and 15-35).

Additionally, new Claim 20 recites that the ligand is specific for equine troponin I, porcine troponin I or bovine troponin I proteins. Applicants respectfully submit that Claim 20 is narrower in scope than Claim 10 and is directed to related subject matter as recognized by the recitation of **duplicate SEQ ID NOs**. Applicants kindly submit that Claim 20 should not be withdrawn from examination because Claim 20 is narrower in scope than pending Claim 10 which itself, is not subject to a further Restriction Requirement.

Applicants also respectfully submit that Claim 20 is within the scope of the Restriction Requirement mailed August 24, 2006, in which applicants elected with traverse to pursue Group

III directed to Claims 10-18 - drawn to an assay for detecting mammalian troponin in a sample. Accordingly, applicants submit Claim 20 is directed to an **elected invention** and kindly request entry and examination of Claim 20.

Claim rejections under 35 U.S.C. §112, first paragraph (new matter)

In the Non-Final Office Action mailed February 5, 2008, the Examiner rejected Claims 10-13 and 15-17 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 10 and 20 are amended herein to clarify that the mammalian troponin molecule is extracted from animal feed to form an **animal feed extract** prior to reacting the animal feed extract with a ligand. Support for the above amendment can be found on page 20, Example 1, lines 4-12 and lines 29-30 of the instant application. Example 1 states that “feed samples known to contain mammalian by-products are obtained and protein is extracted from the sample using methods well known to those of ordinary skill in the art”. For Example, Troponin I is detected in the extract using MT1 or MT2 antibodies in sandwich ELISA procedures, direct ELISA procedures and lateral flow immunochromatography assays. Page 20, lines 29-30 also state that “the diluted feed stock extract containing mammalian troponin protein is subjected to direct bind ELISA using the following procedures”. Applicants respectfully submit the specification as filed provides support for reacting an animal feed extract with a ligand as described above. Accordingly, applicants respectfully submit there is support in the instant specification for an assay for detecting a mammalian troponin molecule in animal feed as claimed herein and kindly request withdrawal of the rejection.

Claim rejections under 35 U.S.C. §112, second paragraph

In the Non-Final Office Action mailed February 5, 2008, the Examiner rejected Claims 10-13 and 15-17 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully submit that the amendments to the claims overcome the rejection.

As discussed above under section 35 U.S.C. §112, first paragraph, Claims 10 and 20 are amended herein to clarify that the mammalian troponin molecule is extracted from the animal feed to form an **animal feed extract** prior to reacting the animal feed extract with a ligand. Support for the above amendment can be found on page 20, Example 1, lines 4-12 and lines 29-30 of the instant application. Accordingly, Applicants respectfully submit the specification as filed provides support for reacting an animal feed extract with a ligand as described above.

In contrast to the Examiner's assertion, applicants submit that one of ordinary skill in the art having read the instant disclosure would be able to make and/or use the claimed invention. Applicants kindly direct the Examiner to Example 1, page 20, lines 4-30, wherein the applicants teach the preparation of an animal feed extract, that is reacted with a ligand. Moreover, the applicants also indicate on page 20, lines 8-11, that ligands MT1 and MT2 are **specific for a mammalian troponin I molecules** and are **not specific for avian troponin I molecules**.

Applicants also direct the Examiner to page 21, lines 11-29, of the instant application that is directed to a lateral flow assay. In this section of the specification, applicants teach the use of MT1 and MT2 (mammalian troponin I molecule specific ligands) that are reacted with the animal feed extract to form a complex. Specifically, the specification recites "for sample analysis 500 μ l of liquid sample is placed into a 1.8 ml microcentrifuge tube. The test strip is placed into the vial where only the sample filter pad contacts the sample. The tests strip is allowed to develop in the sample for ten minutes. Following ten minutes, the tests strip is removed from the sample and the results are interpreted. If two lines are present, the result is positive. If one line is present (at the control zone), the result is negative". Applicants respectfully submit that lateral flow devices and assays are well-known in the art. It is well-known in the art that a positive reaction between a sample and a ligand (for example, an antibody) on a lateral flow device results in the formation of a complex. The complex is often visualized as a colored band, precipitate, signal or in some instances can be observed via spectrophotometric means. The formation of a signal over and above a control reaction on the lateral flow device correlates with a positive determination for the sample being tested. For at least the foregoing reasons, applicants respectfully submit the instant application is enabled with respect to an assay for the detecting a mammalian troponin molecule in animal feed as claimed herein, and kindly request withdrawal of the rejection.

CONCLUSION

Based upon the amendments and remarks provided above, applicants believe that the pending claims are novel and non-obvious. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 815-6473 is respectfully solicited.

Respectfully submitted,

/zara doddrige/

Zara A. Doddrige, Ph.D.
Patent Agent
Reg. No. 59,098

KILPATRICK STOCKTON LLP
Suite 2800
1100 Peachtree Street
Atlanta, GA 30309-4530
Telephone: 404-815-6500
Direct Telephone: 404-815-6473
Facsimile: 404-815-6555
Attorney Docket No. SDI-0571 (45738-296417)